1160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project "The AHRQ Safety Program for Telemedicine: Improving the Diagnostic Process and Improving Antibiotic Use."

DATES: Comments on this notice must be received by (insert date 60 days after date of publication).

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

The AHRQ Safety Program for Telemedicine: Improving the Diagnostic Process and Improving Antibiotic Use

Telemedicine visits increased dramatically in response to the COVID-19 pandemic and resulting changes in third-party payer reimbursement policies. Telemedicine visits increased from 0.3 percent of all ambulatory visits in 2019 to 23.6 percent by Spring 2020. Given this rapid growth, the need to ensure safe and appropriate patient care in this setting is urgent. Telemedicine has many benefits, such as facilitating continuity of care; improving access beyond normal hours; reducing patients' travel burden; overcoming health care provider (HCP) shortages; and providing support for patients managing chronic health conditions. However, transferring clinical practices from an in-person to a virtual environment poses potential risks. Many HCPs have never received formal training in using telemedicine effectively to diagnose and treat patients virtually. Additionally, inadequate internet access, which disproportionately impacts rural and minority populations, and struggles accessing telemedicine platforms may force video-based telemedicine visits to transition to audio-only or be skipped.

This program aims to improve two at-risk areas among telemedicine practices by implementing the AHRQ- and Johns Hopkins Armstrong Institute for Patient Safety and Quality (JHAI)-developed Comprehensive Unit-based Safety Program (CUSP) approach: 1) the diagnostic process for breast, colorectal, and lung cancer; and 2) antibiotic stewardship (AS). The CUSP approach improves safety culture at the practice level, enables harm prevention, and engages providers who are on the front lines while integrating technical and adaptive/cultural approaches to making sustainable changes.

This program constitutes the first large-scale implementation of a quality improvement effort for the cancer diagnostic process and AS in telemedicine. These areas were chosen given the need for clearer guidance and evidence-based telemedicine practices for clinicians and potential for positive impact on outcomes. This program will incorporate CUSP strategies to improve the diagnostic process for breast, colorectal, and lung cancer and to improve antibiotic prescribing in telemedicine. The program goals are to:

- Identify best practices in implementing interventions to improve the cancer diagnostic process and AS in telemedicine.
- Determine how best to adapt CUSP to enhance the cancer diagnostic process and AS in telemedicine.

This study is being conducted by AHRQ through its contractor, NORC at the University of Chicago (NORC) and NORC's subcontractors, the Johns Hopkins Armstrong Institute of Patient Safety and Quality (JHAI) and Baylor College of Medicine (Baylor), pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C 299a(a)(1) and (2)

Method of Collection

To achieve the goals of the AHRQ Safety Program for Telemedicine ("Safety Program"), primary and secondary data collection activities will include:

- 1) Structural Assessment: A brief online assessment will be completed by a leader/champion from each practice to understand practices' infrastructure and capacity to implement the Safety Program.
- 2) AHRQ Office Readiness Survey: A brief online Office Readiness Survey will be completed by all participating staff from each practice in the cancer diagnostic process cohort to understand practices' readiness for implementation of the Safety Program.

- 3) The AHRQ Surveys on Patient Safety Culture: The Medical Office Survey on Patient Safety Culture (MOSOPS) (both cohorts) and a Diagnostic Safety Supplement (cancer diagnostic process cohort only) will be completed by all participating staff to assess patient safety issues, medical errors, and event reporting practices.
- 4) Participant Experience Survey: A brief online assessment will be completed by a leader/champion from each practice to assess how practices approached implementation of the Safety Program.
- 5) Semi-structured Qualitative Interviews: A proportion of practices from both cohorts will be selected to participate in telephone/virtual discussions to understand the facilitators and barriers to implementing the Safety Program.
- 6) Clinical Data Collection Form: Practices in the cancer diagnostic process cohort will complete a Clinical Data Collection Form for patients suspected of having breast, colorectal, or lung cancer.
- 7) Electronic Health Record (EHR) data: Practice-level antibiotic usage and clinical outcomes data will be extracted from the EHRs of practices in the AS cohort.

This data collection effort will be part of a comprehensive evaluation strategy to assess the adoption of the Safety Program among telemedicine practices comprising the cancer diagnostic process and AS cohorts; measure the effectiveness of the Safety Program among the participating practices and evaluate how providers experienced the program as well as the perceived usefulness of the Safety Program's education materials and metrics; and understand drivers of antibiotic prescribing among practices in the AS cohort and drivers of timely diagnosis for patients suspected of having breast, colorectal, or lung cancer among practices in the cancer diagnostic process cohort.

The evaluation is largely formative in nature as AHRQ seeks information on the implementation and effectiveness of CUSP in a novel setting—telemedicine. The evaluation will utilize a pre-

post design, comparing data collected at baseline and at the end of the Safety Program within each cohort.

Estimated Annual Respondent Burden

Exhibit A.1 shows the estimated annualized burden hours for the respondents' time to complete the structural assessments, AHRQ office readiness and patient safety culture surveys, participant experience surveys, semi-structured qualitative interviews, clinical data collection instrument (collected for 3 patients monthly and submitted quarterly), and EHR data extractions (collected monthly and submitted quarterly). Data will be collected from up to 300 practices providing telemedicine for the cancer diagnostic process cohort and from up to 500 practices providing telemedicine for the AS cohort. For the three-year clearance period, the estimated annualized burden hours for the data collection activities are 5,570.

Exhibit A.1. Estimated Annualized Burden Hours

| Form Name | Number of Respondents* | Number of Responses per Respondent | Hours per Response | Total Burden Hours |
|--|---------------------------|--|-----------------------|--------------------------|
| Structural Assessments (both cohorts) | 200 | 2 | 0.2 | 80 |
| 2. AHRQ Office Readiness Survey (cancer diagnostic process cohort only) | 350 | 1 | 0.1 | 35 |
| 3. AHRQ Patient Safety Culture Surveys | | | | |
| a. MOSOPS (both cohorts) | 933 | 2 | 0.5 | 933 |
| b. Diagnostic Safety Supplement (cancer diagnostic process cohort only) | 350 | 2 | 0.2 | 140 |
| 4. Participant Experience Survey (both cohorts) | | | | |

| | a. Cancer diagnostic process cohort survey | 75 | 1 | 0.17 | 13 |
|----|--|-----|----|------|-------|
| | b. AS cohort survey | 125 | 1 | 0.33 | 41 |
| 5. | Semi-structured qualitative interviews (both cohorts) | 24 | 1 | 1 | 24 |
| 6. | Clinical Data Collection Form (cancer diagnostic process cohort) | 90 | 54 | 0.33 | 1,604 |
| 7. | HER data (AS cohort) | 150 | 18 | 1 | 2,700 |
| То | tal | | | | 5,570 |

^{*}Annualized number of respondents is based on maximum practices recruited and 75% response rate for forms 1 and 4a and 4b, 50% response rate for forms 2, 3a and 3b, and 90% response rate for forms 5-7.

Exhibit A.2 shows the estimated annualized cost burden based on the respondents' time to complete the data collection forms. The total cost burden is estimated to be \$576,922.

Exhibit A.2. Estimated Annualized Cost Burden

| Form Name | Number of Respondents* | Total Burden Hours | Average Hourly Wage Rate** | Total Burden Cost |
|---|---------------------------|--------------------------|-------------------------------------|-------------------------|
| Structural Assessments (both cohorts) | 200 | 80 | \$111.30a | \$8,904 |
| 2. AHRQ Office Readiness Survey (cancer diagnostic process cohort only) | 350 | 35 | \$111.30a | \$3,896 |
| 3. AHRQ Patient Safety Culture Surveys: | | | | |
| a. MOSOPS (both cohorts) | | | | |
| i. Physicians | 466 | 466 | \$111.30a | \$51,866 |
| ii. Other Health Practitioners | 467 | 467 | \$31.19 ^b | \$14,566 |
| b. Diagnostic Safety Supplement (cancer | | | | |

| diagnostic process cohort only) | | | | |
|--|-------|-------|-----------------------|-----------|
| i. Physicians | 175 | 70 | \$111.30 ^a | \$7,791 |
| ii. Other Health Practitioners | 175 | 70 | \$31.19 ^b | \$2,183 |
| 4. Participant Experience Survey (both cohorts) | 200 | 54 | \$111.30 ^a | \$6,010 |
| 5. Semi-structured qualitative interviews (both cohorts) | 24 | 24 | \$111.30 ^a | \$2,671 |
| 6. Clinical Data Collection Form (cancer diagnostic process cohort only) | 90 | 1,604 | \$111.30a | \$178,525 |
| 7. EHR data (AS cohort only) | 150 | 2,700 | \$111.30 ^a | \$300,510 |
| Total | 3,497 | 5,582 | | \$576,922 |

^{**}Annualized number of respondents is based on maximum practices recruited and 75% response rate for forms 1 and 4, 50% response rate for forms 2, 3a and 3b, and 90% response rate for forms 5-7.

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the

^{**}National Compensation Survey: Occupational wages in the United States May 2021 "U.S. Department of Labor, Bureau of Labor Statistics:" https://www.bls.gov/oes/current/oes_stru.htm#29-0000

^a Based on the mean wages for 29-1069 Physicians and Surgeons, All Other

^b Based on the mean wages for 29-9099 Miscellaneous Health Practitioners and Technical Workers: Healthcare Practitioners and Technical Workers, All Other

collection of information upon the respondents, including the use of automated collection

techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's

subsequent request for OMB approval of the proposed information collection. All comments

will become a matter of public record.

Dated: December 9, 2022.

Marquita Cullom,

Associate Director.

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